



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,232	12/12/2003	Yosser Ben Achour	02356.0087	4579
22852 7590 09/07/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/733,232

Applicant(s)

BEN ACHOUR ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 19 and 22-53 is/are pending in the application.
- 4a) Of the above claim(s) 1, 5-15 and 23-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 16, 18, 19, 22 and 36-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2007 has been entered.

### ***Amendment Entry***

2. The amendment filed June 25, 2007 has been entered. Claims 1, 4-15 and 23-35 are currently withdrawn. Claims 17 and 20-21 have been canceled. Claims 2-3, 16, 18, 19, 22 and 36-53 are under consideration in this office action.

### ***Withdrawal of Objections and Rejections***

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claims 2-3, 16, 18, 19, 22 and 36-53 under 35 U.S.C. 101;
- b) The objection of claims 3 and 16-22.**

**Response to Arguments**

4. Applicant's arguments filed June 25, 2007 have been fully considered but they are not persuasive.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The written description rejection of claims 2, 16, 18, 19, 22 and 36-53 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Claim 2 is drawn to an isolated or purified protein involved in the virulence of a *Leishmania* parasite, comprising at least one site (Cys-Gly-His-Cys) identical to the potential active site of a protein from the protein disulfide-isomerase family (PDI) wherein said protein is predominantly expressed in the most virulent isolates of the parasite. Claim 46 is drawn to An isolated or a purified protein which is a functional variant of a *Leishmania major* protein disulfide isomerase (LmPDI) protein of *Leishmania major*, wherein the variant has at least 80% identity with SEQ ID NO: 2 and is capable of complementing LmPDI in an infectivity test carried out with an *L. major* strain in which the LmPDI gene has been deactivated. Claims 16, 39 and 47 are drawn

Art Unit: 1645

to immunogenic composition comprising a protein having at least 10 amino acids which is capable of *in vitro* stimulation of the proliferation of mononuclear cells originating from individuals who have come into contact with a *Leishmania major* parasite.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc. that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for broad generic claims, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.*, the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

Claim 2 is drawn to a protein involved in the virulence a *Leishmania* parasite. The written description in this case only sets forth SEQ ID NO:2, therefore the written description is not commensurate in scope with the claim drawn to a protein only described as being involved in *Leishmania* virulence. Neither the specification nor the claims teach the identity of the instantly claimed protein, or immunogenic compositions comprising said protein. Thus applicants were not in possession of the claimed protein.

The specification does not include structural examples. Thus, the resulting protein could result in a protein not taught and enabled by the specification.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Thus, the skilled artisan cannot envision the detailed structure of the isolated protein, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The amino acid sequence itself, or a nucleic acid structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The expression characteristics distinguish the claimed protein only by what it does, i.e., be expressed by the most virulent parasites, however this is a purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The description of its function does not describe the claimed protein itself, nor does it provide the identity of the protein.

See also, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description

Art Unit: 1645

of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus, in the absence of the identity of the protein, a protein described only by its ability to be identical to a potential active site of a protein from a PDI wherein the protein is predominantly expressed in the most virulent isolates of the parasite fails to meet the written description requirements. Therefore only SEQ ID NO:2, and not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

Claim 46 is drawn to a protein with any functional variant of LmPDI having at least at least 80% identity with SEQ ID NO:2. The written description in this case only sets forth specific sequences identified by their SEQ ID Numbers, therefore the written description is not commensurate in scope with the claims drawn to any functional variant. Neither the specification nor the claims teach how to define any functional variant. Neither the claims nor the specification teach how to obtain such any functional variants. There is no guidance as to what the functional variant are; or what functional variant can or cannot be used in the complex being claimed. The specification does not include structural examples. Thus, the resulting functional variant could result in a complexes not taught and enabled by the specification. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the



description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

Contrary to applicants' previous assertions, the variants are defined by the ability to complement LmPDI in an *L. major* strain with a deactivated LmPDI gene. However the written description requirements state that with the exception of specifically identified sequence, the skilled artisan cannot envision the detailed structure of the variants, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it.

Previously, applicants' also urged that genes from other species such as *L. infantum* MC, *L. infantum* Visc, and *L. donovani*, are functional variants which express the LmPDI protein. However it is the examiner's position that none of these proteins share at least 80% identity with SEQ ID NO:2. The finding of a conserved gene does not equate to a protein having a sequence with at least 80% sequence identity to SEQ ID NO:2. Therefore applicants' arguments about structural examples of functional variants are not persuasive since applicants failed to provide a written description of such variants.

Claims 16, 39 and 47 are drawn to immunogenic compositions comprising a protein having at least 10 amino acids. Proteins having at least 10 amino acids fail to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly

Art Unit: 1645

allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The specification discloses SEQ ID NO: 2, there is no disclosure of sequences having 10 or more amino acids within an immunogenic composition which are capable of *in vitro* stimulation. Thus, the structure of these proteins or polypeptides is not defined. A skilled artisan cannot envision the detailed structure of the encompassed molecules. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The amino acid itself is required. There is no support within the specification of an immunogenic composition comprising a polypeptide having 10, 11 or 12 amino acid polypeptide that is capable of the instantly claimed *in vitro* stimulation. The specification does not include structural examples.

Applicants' have asserted that pages 6-7 of the instant specification provide support for the polypeptide. However it is the examiner's position that the specification merely provides a broad definition of polypeptide and fails to provide a written description of an immunogenic composition comprising a polypeptide having 10, 11 or 12 amino acid polypeptide that is capable of the instantly claimed *in vitro* stimulation. Thus, applicants' arguments are not persuasive.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of a *Leishmania* protein involved in the

Art Unit: 1645

virulence of the parasite, comprising at least one site (Cys-Gly-His-Cys) identical to the potential active site of a protein from the protein disulfide-isomerase family (PDI) comprised within an immunogenic composition being capable of *in vitro* stimulation of the proliferation of mononuclear cells originating from individuals who have come into contact with a *Leishmania major* parasite or capable of inducing an immune response of the Th1 type when administered to a human or animal host. The protein is also comprised within an immunogenic composition wherein the compositions is being intended to protect a human or animal host against leishmaniasis, and having a pharmaceutically acceptable formulation for administration to a human or animal host. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

6. The enablement rejection of claims 2, 16, 18, 19, 22 and 36-53 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

Claim 2 is drawn to an isolated or purified protein involved in the virulence of a *Leishmania* parasite, comprising at least one site (Cys-Gly-His-Cys) identical to the potential active site of a protein from the protein disulfide-isomerase family (PDI) wherein said protein is predominantly expressed in the most virulent isolates of the parasite. Claim 46 is drawn to An isolated or a purified protein which is a functional variant of a *Leishmania major* protein disulfide isomerase (LmPDI) protein of *Leishmania major*, wherein the variant has at least 80% identity with SEQ ID NO: 2 and is capable of complementing LmPDI in an infectivity test carried out with an *L. major* strain in which the LmPDI gene has been deactivated. Claims 16, 39 and 47 are drawn

Art Unit: 1645

to immunogenic composition comprising a protein having at least 10 amino acids which is capable of *in vitro* stimulation of the proliferation of mononuclear cells originating from individuals who have come into contact with a *Leishmania major* parasite.

As to the asserted use of a *Leishmania* protein, the specification lacks a clear demonstration that the protein of the instant claims is suitable for immunization. The specification states, at example 5 is drawn to using a recombinant LmPDI protein, however that passage does not provide support for administering a protein comprising only 10 amino acids and eliciting the claimed responses. Therefore applicants' amendments to recite polypeptides having at least 10 amino acids do not overcome the rejection. Thus there is no evidence that the instantly claimed protein, absent the same components will function at all to induce an immune response. There is no evidence that antibody production was elicited after administration of a polypeptide with at least 80% sequence identity to SEQ ID NO:2. Therefore the effects of these changes are largely unpredictable and likewise present is the unreliable correspondence between the claimed protein and the recited administration of the LmPDI polypeptide, thus there is no support for the claims regarding enablement.

Absent clear demonstration of an immune response by a mammal as a result of receiving an immunogenetically effective amount of the protein, the protein could not be used in any well-established manner for inducing an immune response. In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate reagents are required, whether antibodies are even produced and whether this protein will function as an immunogen.

Art Unit: 1645

Claim 46 is drawn to a functional variant LmPDI protein of *Leishmania major*, having at least 80% identity with LmPDI. However absent factual evidence, a percentage sequence similarity of less than 100% is not deemed to reasonably support, to one skilled in the art, as to whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule.

The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. The previously cited art teaches that replacement of a single amino acid residue may lead to both structural and functional changes in the biological activity of a protein. One of skill in the art would be reduced to merely randomly altering amino acids which would lead to unpredictable results regarding the functional activity of the polypeptide and the ability of the polypeptide to elicit an immune response. The art is replete with examples that even one amino acid change can lead to unpredictable changes in the biological activity of the protein. Therefore, the recitation of similar sequence identity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecules and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement.

Claims 16, 39 and 47 are drawn to immunogenic compositions comprising a protein having at least 10 amino acids. However in the absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate additions, deletion and substitutions would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine

Art Unit: 1645

experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of a sequence having at least 10 amino acids. The additions/deletions, substitutions or insertions of any amino acid in any location within the protein would not predictably result in an enabled polypeptide. The specification does not provide guidance on how any amino acids can be substituted or inserted for the production of a polypeptide nor does the specification provide guidance on how any location can be used to produce a stable polypeptide. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which substitutions or insertions or any combination would result in the desired polypeptide. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino at any location to produce such proteins. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use for isolated polypeptides. Accordingly, the specification is not enabled for using the alleged protein in any manner disclosed. Therefore, a skilled artisan would be forced into undue experimentation to practice (i.e., make and use) the invention as is broadly claimed.

Art Unit: 1645

7. Claims 2-3, 16, 18, 19, 22 and 36-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The phrase "protein is predominantly expressed most virulent" in claims 2-3 is a relative term which renders the claims indefinite. The phrase is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase is relative, since the standard from determining predominant expression and most virulent isolates is not defined. Thus the metes and bound of the term cannot be ascertained and clarification is required to overcome the rejection.

b) The phrase "involved in the virulence of a Leishmania parasite" in claims 2-3 is a relative term which renders the claims indefinite. The phrase is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase is relative, since the standard from determining the involvement of the protein in virulence is not defined. Thus the metes and bound of the term cannot be ascertained and clarification is required to overcome the rejection.

c) The phrase "potential active site" in claims 2-3 is a relative term which renders the claims indefinite. The phrase is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase is

Art Unit: 1645

relative, since the standard from determining what a potential active is is not defined. Thus the metes and bound of the term cannot be ascertained and clarification is required to overcome the rejection.

d) Claim 19 recites the limitation "the Th1 type" in the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Objections***

8. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 recites "SEQ ID No: 2", instead of "SEQ ID NO:2". Therefore clarification is required to overcome the objection.

9. Claims 16,18-19, 22 and 36-53 are objected to because of the following informalities: Dependant claims refer to "A isolated protein" "a protein" or "An immunogenic composition" however the suggested claim language is to use of the article "The." Therefore the suggested claim language is "The isolated protein" "the protein" or "The immunogenic composition." Appropriate clarification is required to overcome the rejection.



Art Unit: 1645

10. Claims 19, 36, 41, 42, 49 and 50 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims do not add any additional components to the immunogenic composition. The capability of the immunogenic composition to be capable of inducing an immune response of the Th1 type when administered does not add any structural limitation to the composition. Therefore clarification is required to overcome the objection.

### ***Conclusion***

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
August 30, 2007



MARK NAVARRO  
PRIMARY EXAMINER